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April 12, 2000

BY FACSIMILE

The Honorable Jane E. Henney
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: Docket 99N-4783

Dear Commissioner Henney:

I am writing to comment on the Food and Drug Administration's (FDA's) proposed rule entitled "Administrative Practices and Procedures, Good Guidance Practices" (GGPs), published in the Federal Register on February 14, 2000 (65 Fed. Reg. 7321).

I have long been concerned about FDA's development and use of non-codified guidance documents and other informal agency statements. On September 14, 1995, I chaired a hearing on the citizen's petition filed by the Indiana Medical Device Manufacturers Council to reform FDA's development and use of guidance documents. This proposed rule represents an important structural reform. I applaud FDA for recognizing the need to increase training and for focusing on changing the attitude of its personnel to ensure that nonbinding guidance documents are not used to impose new mandatory requirements.

The GGPs proposed rule implements section 405 of the FDA Modernization Act of 1997 (FDAMA), which amended the Federal Food, Drug and Cosmetic Act (FD&C Act) by adding a new section 701(h). This section requires FDA to codify its informal GGPs by July 1, 2000. This section also directs FDA to develop guidance documents with public participation and ensure that they are readily available to the public in written and electronic form. FDA's GGPs proposed rule is a step in the right direction toward implementing these Congressional directives. However, I have the following five specific concerns.

First, FDA must refrain from using non-codified guidance documents as a substitute for rulemaking under the Administrative Procedure Act (APA). The legal protections provided in the

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APA and other laws governing rulemaking procedure (e.g., the Regulatory Flexibility Act) ensure that interested parties and the public can participate meaningfully in the development of binding regulations. Moreover, rules and guidance documents with general applicability or legal effect are subject to Congressional review under the Congressional Review Act. Public and Congressional participation in rulemaking helps develop better rules and is a hallmark of our democratic system of government.

Second, FDA's GGPs proposed rule does not clearly inform the regulated community and the public that guidance documents are not legally binding. The proposed GGPs rule would require that all guidance documents include basic identifying information, including a statement explaining their nonbinding legal effect (proposed 21 C.F.R. § 110.15(i)). However, it does not require that the statement be displayed prominently, in a place (e.g., the beginning of the document), where readers will be certain to see it. Requiring such a statement is important, and I support this approach. In fact, I introduced a bill in this Congress, H.R. 3521, entitled "The Congressional Accountability for Regulatory Information Act of 2000," which would require Federal agencies to include in the beginning of their guidance documents a statement of their nonbinding effect. When requiring such important disclosures, FDA often mandates that they be prominent, e.g., 21 C.F.R. § 101.15 (Food; prominence of required statements). I urge FDA to revise the proposal to require that the basic information required in all guidance documents, including the statement of nonbinding effect, be displayed prominently.

Third, FDA's GGPs proposed rule does not adequately encourage FDA to seek public participation before FDA solidifies its views and creates a draft guidance document. FDAMA section 405 requires FDA to "develop guidance documents with public participation." Collaboration with interested parties and the public about approaches to a problem or issue is likely to be more meaningful when done early in the process and before FDA settles on an approach. Early public participation is essential to the legitimacy of allowing unelected administrators to make public policy decisions. Therefore, I urge FDA to revise its proposal to actively encourage such pre-proposal collaboration by substituting "shall" for "may" and "and" for "or" in its proposed section on collaboration. Thus, 21 C.F.R. § 10.115(g)(1)(i) would read: "Before FDA prepares a draft of a Level 1 guidance document, FDA **shall** seek **and** accept early input from individuals or groups outside the agency...."

Fourth, FDA's proposed rule on GGPs proposes to retreat to publishing FDA's Guidance Development Agenda to only once per year, instead of twice, and FDA does not prioritize topics for guidance development. The useful Unified Agenda of Federal Regulatory and Deregulatory Actions is published twice a year; FDA should follow this practice. Interested parties and the public need information about FDA's priorities to participate meaningfully in guidance development. I do not think collecting and providing this minimal information to interested parties and the public is that burdensome. For example, the Center for Food Safety and Applied Nutrition already issues similar annual priority agendas and such priority setting should be done generally by FDA as a management tool. Moreover, under our democratic system of government, the people have a fundamental right to know the priorities of regulatory officials.

Finally, FDA's GGPs proposed rule fails to implement the FDAMA section 405 requirement that FDA identify an appeal process for substantive concerns about a guidance document. The GGPs proposed rule identifies an appeal process only when **procedural** requirements of the GGPs were not

followed (proposed 21 C.F.R. § 10.115(o)). I urge FDA to include in the rule a cross-reference to 21 C.F.R. § 10.75, the normal appeal process for FDA decisions, to clarify that this section also applies to appeals about the **substantive** content of guidance documents.

Thank you for considering my comments on your proposed rule.

Sincerely,

David M. McIntosh
Chairman
Subcommittee on National Economic Growth, Natural Resources, and Regulatory Affairs

cc: The Honorable Dan Burton
The Honorable Dennis Kucinich